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(54) **DEVICE AND METHOD FOR OPERATING A TOOL RELATIVE TO BONE TISSUE AND DETECTING NEURAL ELEMENTS**

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(52) **U.S. Cl.**
USPC **606/80**

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See application file for complete search history.

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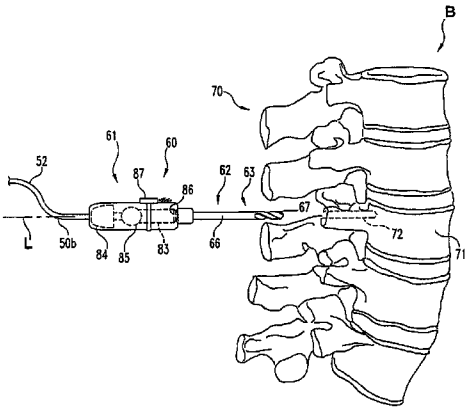
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(57) **ABSTRACT**

An apparatus for providing medical treatment includes a tool portion configured to operate relative to bone tissue, a handle portion to operate the tool portion, and a nerve monitoring system to detect neural elements. The tool portion includes an insulated shaft comprised of an electrically conductive member and a non-insulated tip. The shaft carries an electrical signal to the non-insulated tip. The handle portion, which is removably and operably connected to the tool portion, incorporates an operating system to rotationally operate the tool portion. Additionally, the nerve monitoring system is linked to the tip and is operable to detect a neural element as a function of a characteristic of the electrical signal on the tip. Upon detection of a neural element, the nerve monitoring system provides a signal to the operating system of the handle portion directing the operating system stop rotation of the tool portion.

5 Claims, 4 Drawing Sheets



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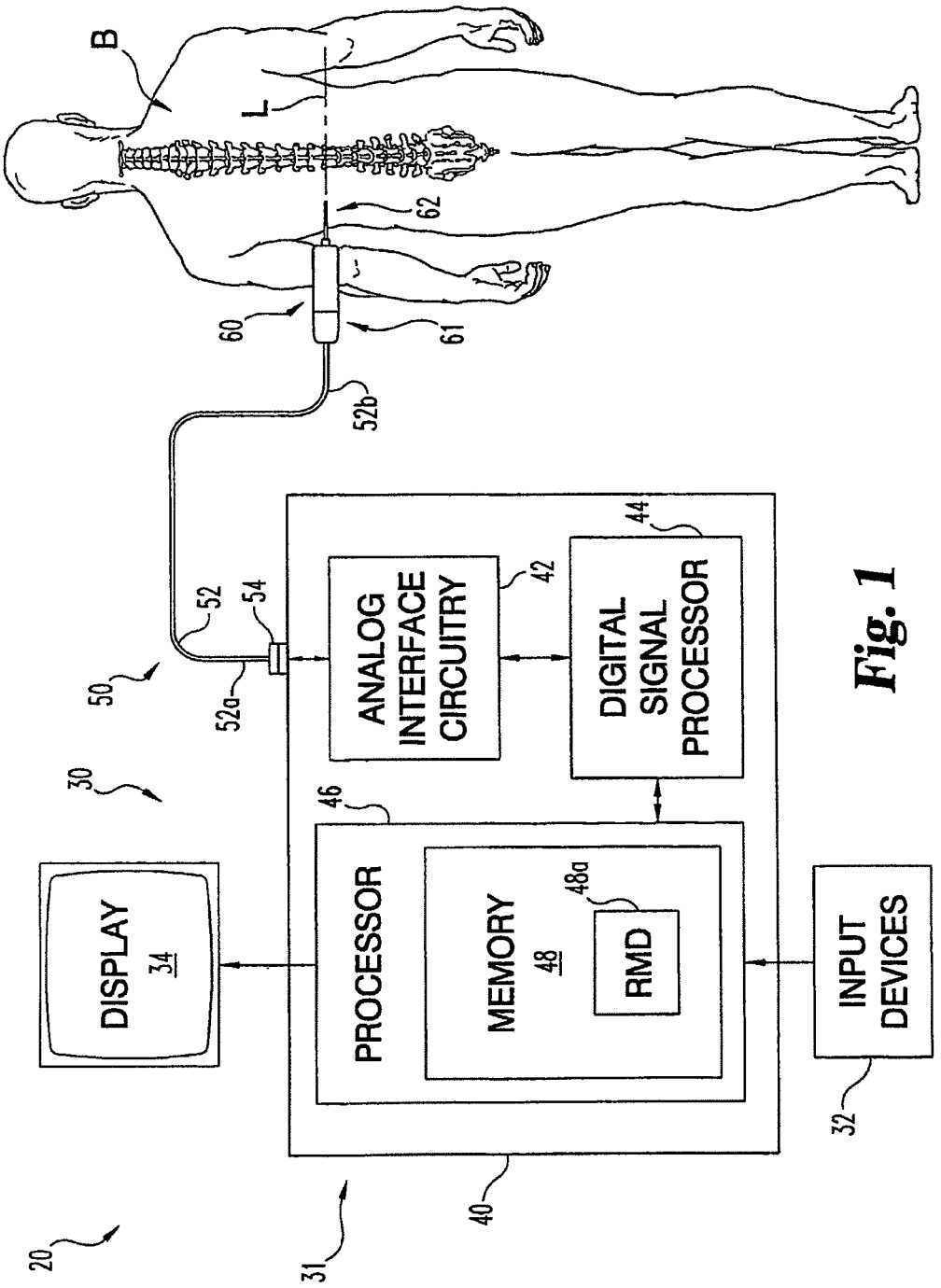

B
L
62
60
61
52b
52
54
52a
50
30
ANALOG INTERFACE CIRCUITRY
42
DIGITAL SIGNAL PROCESSOR
44
46
PROCESSOR
MEMORY
48
48a
RMD
DISPLAY
34
INPUT DEVICES
32
40
31
20

Fig. 1

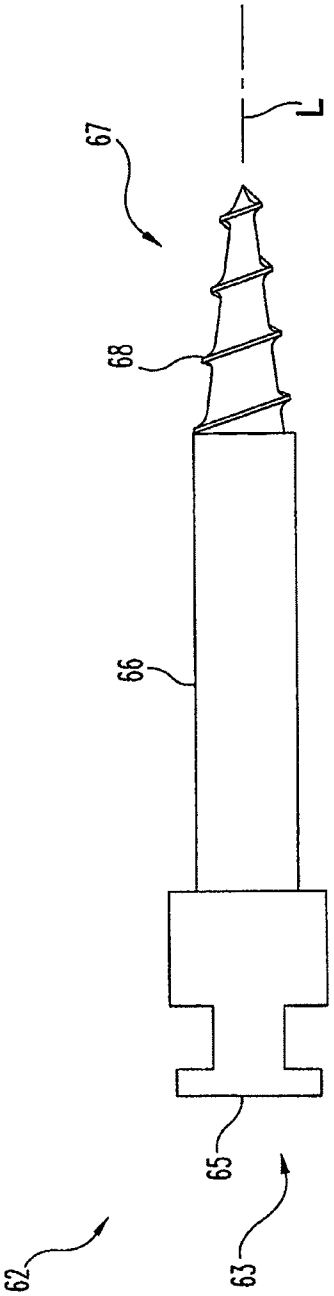


Fig. 2A

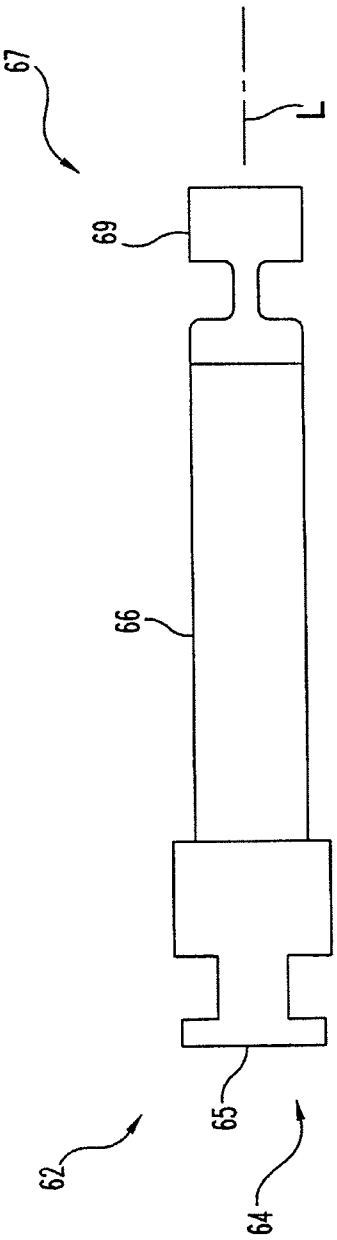


Fig. 2B

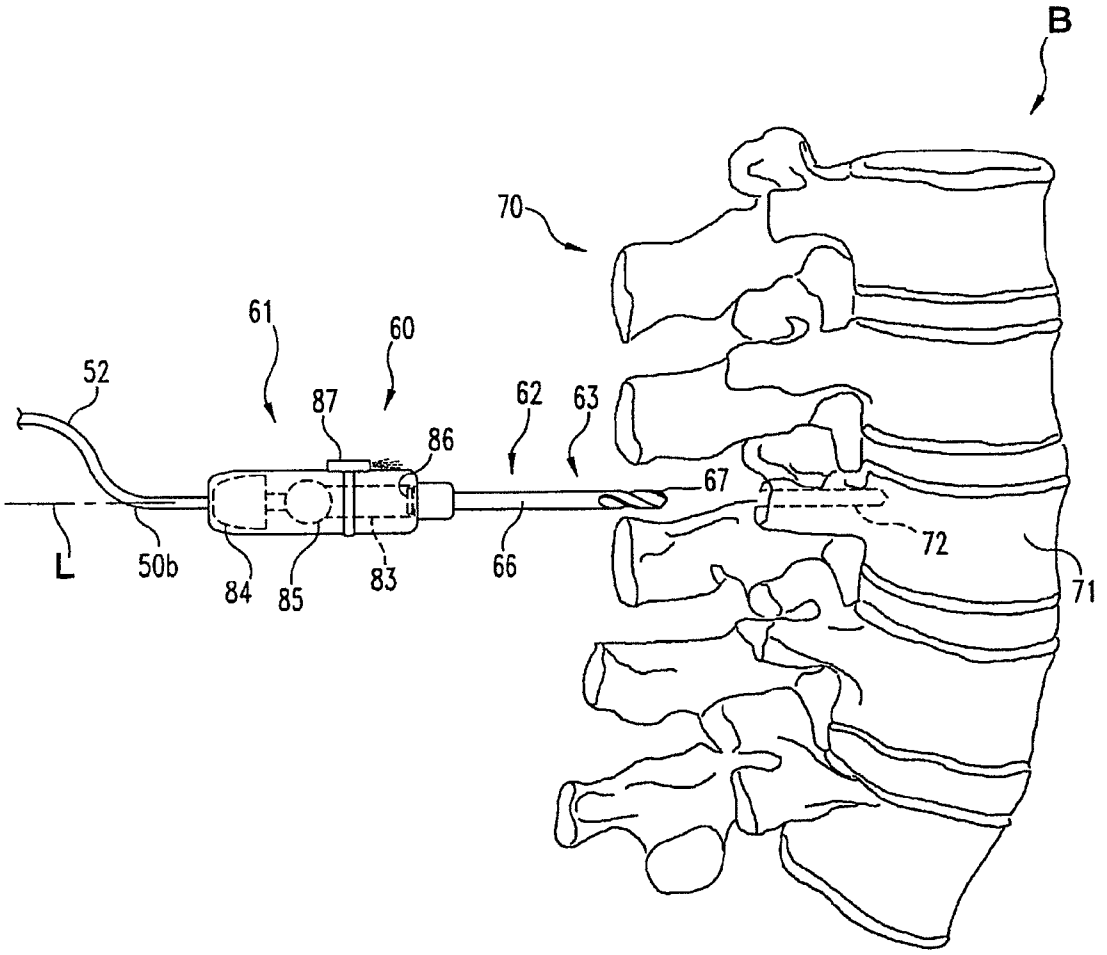


Fig. 3

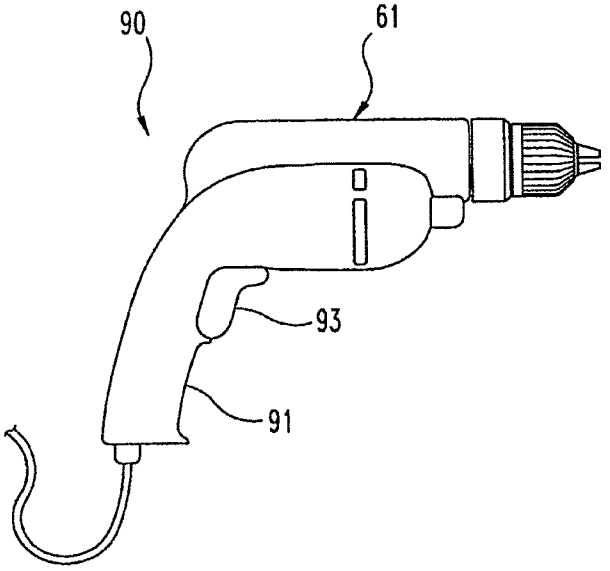


Fig. 4A

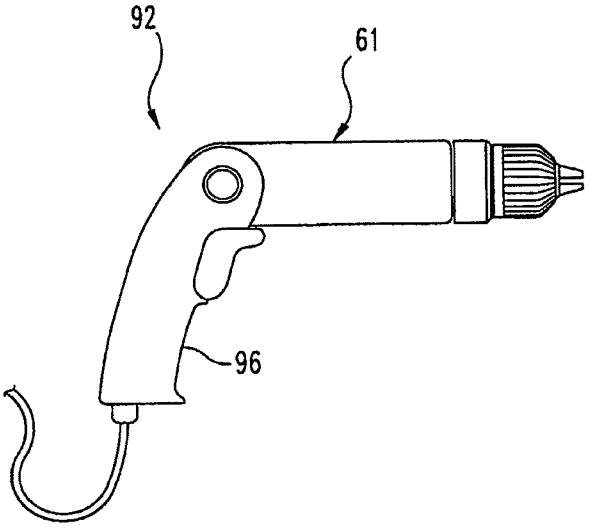


Fig. 4B

DEVICE AND METHOD FOR OPERATING A TOOL RELATIVE TO BONE TISSUE AND DETECTING NEURAL ELEMENTS

This application is a continuation of co-pending U.S. patent application Ser. No. 11/052,641, filed Feb. 7, 2005, which is incorporated herein by reference.

BACKGROUND

Surgery for a patient can be painful and traumatic, particularly in the affected area of the patient's body. To accomplish spinal fixation, a necessary procedure often involves forming a hole in a pedicle wall of a vertebra in a patient's spine and inserting a spinal pedicle screw into the hole. Pedicle screws are advantageous in that they are strong and provide stability, however, care must be taken to avoid nerve impingement during formation of the holes and the placement of pedicle screws in the spine. Measures taken to simultaneously monitor and locate any neural elements can facilitate hole formation and screw insertion.

Locating defects such as openings in bone tissue that expose nerves can be difficult. Some procedures involve monitoring muscle reactions to electrical stimulation to locate nerves in an area of bone tissue. If a nerve is not located and a screw contacts an exposed nerve, the screw can impinge on the nerve or become too close to the nerve root causing pain and other implications for the patient. Locating neural elements during the hole formation and screw insertion processes can facilitate such surgical procedures.

There remains a need for instruments and methods that can be employed for locating neural elements during formation of a hole in the pedicle wall and/or insertion of a screw therein. The present invention is directed to meeting these needs, among others.

SUMMARY

According to one aspect, an apparatus is provided comprising a tool portion configured to operate relative to bone tissue, a handle portion to operate the tool portion, and a nerve monitoring system to detect neural elements. The tool portion includes an insulated shaft comprised of an electrically conductive member and a non-insulated tip. The shaft carries an electrical signal to the non-insulated tip. The handle portion, which is removably and operably connected to the tool portion, incorporates an operating system to operate the tool portion. Additionally, the nerve monitoring system is connected to the handle portion and is operable to detect a neural element as a function of a characteristic of the electrical signal at the tip. Upon detection of a neural element, the nerve monitoring system provides a signal to the operating system of the handle portion directing the operating system to change an operative mode of the tool portion.

Another aspect involves an apparatus comprising a tool portion configured to operate relative to bone tissue and a handle portion removably and operably coupled to the tool portion including a system for rotating the tool portion. The tool portion includes an elongated insulated shaft and a non-insulated tip at a distal end of the shaft. The shaft is comprised of an electrically conductive member. The operating system in the handle portion is operable to change an operative mode of the tool portion in response to the detection of neural elements via an electrical signal at the tip of the tool portion.

Yet another aspect involves a method comprising providing a handle portion, which incorporates an operating system, and connecting a tool portion to the handle portion. The tool portion includes an insulated shaft and a non-insulated tip. Additionally, the operating system is operable to rotate the tool portion about a longitudinal axis. The method further comprises providing a nerve monitoring system operably connected to the handle portion, providing an electrical signal to the tip, and rotating the tool portion relative to bone tissue. The nerve monitoring system provides an indication of the detection of a neural element as a function of the electrical signal. Upon detection of the neural element in the bone tissue, the nerve monitoring system sends a signal to the operating system of the handle portion to stop rotation of the tool portion.

Another aspect involves a system comprising a tool portion, a handle portion, and a nerve monitoring system. The tool portion includes an insulated shaft extending along a longitudinal axis and a non-insulated tip. The handle portion is operably and rotatably coupled to the tool portion and configured to rotate the tool portion relative to the handle portion. The nerve monitoring system is electrically coupled to the tool portion to provide an electrical signal to the tip to detect neural elements proximate the tip of the tool portion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic view of a medical system.

FIG. **2**A is a schematic view of one embodiment attachment to a handle device.

FIG. **2**B is a schematic view of another embodiment tool attachment to a handle device.

FIG. **3** is a partial, schematic view of a tool and handle device relative to a section of a spine.

FIG. **4**A is a schematic view of another embodiment handle device.

FIG. **4**B is a schematic view of another embodiment handle device

DETAILED DESCRIPTION

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is hereby intended, such alterations and further modifications in the illustrated devices, and such further applications of the principles of the invention as illustrated herein being contemplated as would normally occur to one skilled in the art to which the invention relates.

An apparatus for providing medical treatment includes a tool portion configured to operate relative to bone tissue, a handle portion to operate the tool portion, and a nerve monitoring system to detect neural elements. The tool portion includes an insulated shaft comprised of an electrically conductive member and a non-insulated tip. The shaft carries an electrical signal to the non-insulated tip. The handle portion, which is removably and operably connected to the tool portion, incorporates an operating system to operate the tool portion. Additionally, the nerve monitoring system is connected to the handle portion and is operable to detect a neural element as a function of a characteristic of the electrical signal in the tip. Upon detection of a neural element, the nerve monitoring system provides a signal to the operating system of the handle portion directing the operating system to change an operative mode of the tool portion.

FIG. **1** illustrates system **20** that includes a medical device and associated equipment arranged to provide medical treatment. System **20** is arranged to create holes and insert bone

screws in a pedicle wall of one or more vertebrae of spinal column B. Further, system **20** is arranged to provide nerve monitoring and change an operative mode of the device creating the hole or inserting the screw upon detection of a neural element. The change in operative mode can include stopping rotation of the tool portion and/or reversing rotation of the tool portion and allow for removal of the device from the bone tissue upon detection of a neural element.

System **20** includes nerve monitoring system **30**, connection link **50**, and medical device **60**. Device **60** extends generally along a longitudinal axis L and includes a handle portion **61** and a tool portion **62**. Nerve monitoring system **30** includes equipment **31** coupled to device **60** with connection link **50** or integrated with device **60**. Device **60** is configured for operation relative to a spinal pedicle wall of spinal column B of a human patient or subject, as schematically represented in FIG. **1**. One example of a suitable system **30** is the NIM-Spine® System marketed by Medtronic, Inc.

Equipment **31** may include operator input devices **32**, operator display device **34**, and various other operator-utilized equipment of system **20** that is external to a patient during use. Input devices **32** may include an alphanumeric keyboard and mouse or other pointing device of a standard variety. Alternatively or additionally, one or more other input devices can be utilized, such as a voice input subsystem or a different type as would occur to those skilled in the art. Operator display device **34** can be of a Cathode Ray Tube (CRT) type, Liquid Crystal Display (LCD) type, plasma type, Organic Light Emitting Diode (OLED) type, or such different type as would occur to those skilled in the art. Alternatively or additionally, one or more other operator output devices can be utilized, such as a printer, one or more loudspeakers, headphones, or such different type as would occur to those skilled in the art. Nerve monitoring system **30** also can include one or more communication interfaces suitable for connection to a computer network, such as a Local Area Network (LAN), Municipal Area Network (MAN), and/or Wide Area Network (WAN) like the Internet; a medical diagnostic device; another therapeutic device; a medical imaging device; a Personal Digital Assistant (PDA) device; a digital still image or video camera; and/or audio device, to name only a few. Nerve monitoring system **30** can be arranged to show other information under control of the operator.

Equipment **31** may also include processing subsystem **40** for processing signals and data associated with system **20**. Subsystem **40** may include analog interface circuitry **42**, Digital Signal Processor (DSP) **44**, data processor **46**, and memory **48**. Analog interface circuitry **42** can be responsive to control signals from DSP **44** to provide corresponding analog stimulus signals to device **60**. At least one of analog interface circuitry **42** and DSP **44** may include one or more digital-to-analog converters (DAC) and one or more analog-to-digital converters (ADC) to facilitate operation of system **20** in the manner to be described in greater detail hereinafter. Processor **46** can be coupled to DSP **44** to bidirectionally communicate therewith, selectively provide output to display device **34**, and selectively respond to input from operator input devices **32**.

DSP **44** and/or processor **46** can be of a programmable type; a dedicated, hardwired state machine; or a combination of these. DSP **44** and processor **46** perform in accordance with operating logic that can be defined by software programming instructions, firmware, dedicated hardware, a combination of these, or in a different manner as would occur to those skilled in the art. For a programmable form of DSP **44** or processor **46**, at least a portion of this operating logic can be defined by instructions stored in memory **48**. Programming of DSP **44** and/or processor **46** can be of a standard, static type; an adaptive type provided by neural networking, expert-assisted learning, fuzzy logic, or the like; or a combination of these.

Memory **48** is illustrated in association with processor **46**; however, memory **48** can be separate from or at least partially included in one or more of DSP **44** and processor **46**. Memory **48** includes at least one Removable Memory Device (RMD) **48***a*. Memory **48** can be of a solid-state variety, electromagnetic variety, optical variety, or a combination of these forms. Furthermore, memory **48** can be volatile, nonvolatile, or a mixture of these types. Memory **48** can be at least partially integrated with circuitry **42**, DSP **44**, and/or processor **46**. RMD **48***a* can be a floppy disc, cartridge, or tape form of removable electromagnetic recording media; an optical disc, such as a CD or DVD type; an electrically reprogrammable solid-state type of nonvolatile memory, and/or such different variety as would occur to those skilled in the art. In still other embodiments, RMD **48***a* is absent.

Circuitry **42**, DSP **44**, and processor **46** can be comprised of one or more components of any type suitable to operate as described herein. Further, it should be appreciated that all or any portion of circuitry **42**, DSP **44**, and processor **46** can be integrated together in a common device, and/or provided as multiple processing units. For a multiple processing unit form of DSP **44** or processor **46**; distributed, pipelined, and/or parallel processing can be utilized as appropriate. In one embodiment, circuitry **42** is provided as one or more components coupled to a dedicated integrated circuit form of DSP **44**; processor **46** is provided in the form of one or more general purpose central processing units that interface with DSP **44** over a standard bus connection; and memory **48** includes dedicated memory circuitry integrated within DSP **44** and processor **46**, and one or more external memory components including a removable disk form of RMD **48***a*. Circuitry **42**, DSP **44**, and/or processor **46** can include one or more signal filters, limiters, oscillators, format converters (such as DACs or ADCs), power supplies, or other signal operators or conditioners as appropriate to operate system **20** in the manner to be described in greater detail hereinafter.

In one embodiment, connection link **50** includes a link **52** in the form of a flexible cable with a proximal end **52***a* and an opposite distal end **52***b*. A connector **54** is electrically connected to equipment **31** of nerve monitoring system **30**. Link **52** extends from connector **54** at proximal end **52***a* to distal end **52***b* where it is connected with device **60**. Connection link **50** may include forms in addition to or in alternative to link **52**, including one or more wires, cords, wireless links, infrared components, bluetooth, or other communication link. Further, it should be appreciated that other components, devices, and systems can be integrated into system **20**, such as an endoscope system, a catheterization system, an imaging system, a lighting system, and/or a video camera system, to name a few examples. Connection link **50** and device **60** are movable toward and away from spinal column B in a surgical procedure that may include one or more of retractors, tubes, sleeves, guards, micro-incisions or other components not shown to enhance clarity.

In FIGS. **1** and **3**, tool portion **62** includes a configuration suitable for use as a drill to cut and remove bone material to form a hole to receive a bone anchor. FIGS. **2**A and **2**B illustrate views of alternate embodiments of the components of tool portion **62**. As examples, tool portion **62** can be a tap **63** (FIG. **2**A) or a screw driver **64** (FIG. **2**B.) Each tool portion **62** generally includes a universal connector **65** at its proximal end, a shaft **66**, and a non-insulated tip **67** at a distal end. Universal connector **65** may include any suitable configura-

tion for releasable connection with handle portion **61**. In the illustrated embodiment, tap **63** includes a tapping head **68** at a distal end thereof configured to form a tapped hole pattern to receive a threaded portion of a bone anchor. Screw driver **64** includes driver head **69** at a distal end thereof that may include any suitable configuration for positioning in or about a screw, bolt or other device to be implanted in the pedicle with application of rotary force.

It should be appreciated that tip **67** can be other any other dissection or resection tool that performs a function relative to spinal column B. In the illustrated embodiment, tool portion **62** is generally cylindrically shaped about longitudinal axis L. Universal connector **65** and shaft **66** are composed of an electrically conductive material with an insulative member or coating thereabout to prevent shunting of electricity delivered therethrough to adjacent tissue or devices. Tip **67** is not insulated so that it is exposed to the adjacent bone tissue and carries an electrical signal for detection of nerve proximity.

FIG. **3** illustrates the components of one embodiment of device **60** and the relationship of device **60** to a vertebra **71** in segment **70** of spinal column B. Handle portion **61** is generally cylindrically shaped and elongated about longitudinal axis L. Handle portion **61** generally includes an operating system or set of operating equipment to perform functions during the operation of system **20**. Handle portion **61** is composed of an insulative member or coating surrounding an electrically conductive shaft **83**. The insulative member or coating thereabout allows handling of handle portion **61** and prevents shunting of electricity delivered therethrough to adjacent tissue or devices.

In one embodiment, handle portion **61** carries a circuit **84** and a motor **85** which operates to rotate shaft **83** and tool portion **62** coupled thereto about longitudinal axis L. Shaft **83** includes a rotatable coupling member **86** at a distal end thereof to operably connect with universal connector **65** of tool portion **62**. It should be appreciated that handle portion **61** and tool portion **62** can be operably, rotatably, and electrically coupled together by any appropriate means, including interference fits, fasteners, chucks, and ball-detent mechanisms, for example. Additionally, handle portion **61** can be operable to provide an indication when tool portion **62** is coupled thereto. Device **60** can further include a light assembly **87** to illuminate an area of bone tissue of vertebra **71** or provide light to hole **72** in bone tissue of vertebra **71**. Light assembly **87** can include a removable clip-on type element, or can be formed as an integral unit with handle portion **61**.

Tool portion **62** can be provided in electrical engagement with a source for an electrical signal to locate neural elements proximate tool portion **62**. For example, an electrical lead can extend from tool portion **62**, through handle portion **61**, to nerve monitoring system **30** for coupling with a source of electrical current either separately from or as a part of connection link **50**. The electrical current is delivered to tip **67** to allow monitoring and detection of neural elements based on the proximity and response of the neural elements to the electrical signal. In the embodiment illustrated in FIG. **3**, tool portion **62** is a drill configured for creation of hole **72** during use. During creation of hole **72**, tip **67** carries an electrical signal that provides an indication of the proximity of neural elements in the bone tissue relative to the tip **67** during formation of the hole **72**. Other embodiments contemplate tool portions that allow detection of nerve proximity during tapping of hole **72** and during insertion of an anchor into hole **72**. One example of a surgical probe and procedure for detecting neural elements is provided in U.S. Pat. No. 5,474,558 to Neubardt, which is incorporated herein by reference in its entirety.

In FIG. **2** handle portion **61** is shown in cylindrical form. FIGS. **4**A and **4**B illustrate alternative handle configurations for use with handle portion **61**. For example, handle **90** is provided with a pistol grip portion **91** that removably receives or is integrally formed with handle portion **91**. Pistol grip portion **91** includes a trigger **93** operable coupled to handle portion **61** that facilitates user to control operation of tool portion **62** and facilitates positioning and maintaining handle portion **61** in the desired position during the surgical procedure. In FIG. **4**B, handle **92** includes a pistol grip configuration with a pistol grip portion **96** pivotally coupled to handle portion **61**. The pivotal connection allows a change of attitude of handle portion **61** relative to the gripping portion **96** and facilitates control and repositioning of the instrument during the surgical procedure as may be needed to accommodate the surgical approach, tool portions, and instruments employed with handle portion **61**.

Generally referring to FIGS. **1-4**, the operation of system **20** includes attaching a selected tool portion **62** to handle portion **61** by engaging universal connector **65** with coupling member **86** of handle portion **61**. Surgical access is provided to an area of bone tissue which, in one embodiment, is an area of tissue within a spinal pedicle wall of vertebra **71** of spinal segment **70**. Nerve monitoring system **30** provides an electrical signal to tip **67** of tool portion **62**. Circuit **84** and motor **85** are operable to rotate tool portion **62** about longitudinal axis L. In one embodiment, the rotation of tool portion **62** occurs at a relatively low speed with a relatively high torque to facilitate removal of bone tissue while preventing rapid advancement of the tool portion into the bone tissue during formation, tapping or anchor insertion relative to hole **72**.

In one embodiment, the electric signal in tip **67** provides electrical stimulation to the tissue surrounding hole **72**, and the patient response to the nerve stimulation is monitored to determine whether a neural element threshold has been reached. The threshold can correspond to, for example, an indication of the presence a neural element and its proximity relative to tip **67**. In another embodiment, when tip **67** is positioned near or proximate a neural element, in certain situations, the presence of the neural element creates an electrical current path for the signal carried by tip **67**. The current path provides an indication to nerve monitoring system **30** of the presence of the neural element, and corrective action can then be taken by the surgeon based on this indication. In other words, detection of the neural element threshold occurs as a function of the electrical signal at tip **67** inducing a reaction in the patient or particular reading at the threshold. The threshold causes a signal from the nerve monitoring system **30** to device **60** that changes an operative mode of device **60**.

In one embodiment, upon detection of a neural element within a predetermined proximity of tip **67**, nerve monitoring system **30** is operable send a signal to circuit **84** that stops operation of motor **85** in handle portion **61**, stopping rotation of tool portion **62**. Thus, system **20** operates to automatically stop rotation and operation of tool portion **62** to prevent further advancement of the tool portion or anchor into the bone tissue. In another embodiment, upon receipt of the stop signal circuit **84** functions to automatically reverse the direction of rotation of tool portion **62** to facilitate withdrawal of or backing up of tool portion **62** from the bone tissue. If no neural element is detected, the operation of tool portion **62** continues until successful completion of hole formation and/or bone screw insertion.

In one embodiment, tool portion **62** is autoclavable for re-use after a particular use. In another embodiment, tool portion **62** is disposable after each use, and a different tool portion **62** is inserted into handle portion **61** for further opera-

tion of system **20**. In still another embodiment, the entire device **60** is disposable. In an another embodiment, nerve monitoring system **30** is absent from system **20** and an operating system within handle portion **61** is operable to detect neural elements and provide signals to circuit **84** to stop operation of tool portion **62**. It should be appreciated that other steps or stages can be incorporated into the operating procedure of system **20**, or the steps of operation of system **20** can be arranged differently in order to complete the surgical procedure.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. All changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A surgical method, comprising:

providing a handle portion incorporating an operating system;

connecting a tool portion to the handle portion, wherein the tool portion includes an insulated shaft and non-insulated tip, and wherein the handle portion is configured to electrically insulate a user of the tool portion from an electrical signal induced at the tip; wherein the operating system is operable to rotate the tool portion about a longitudinal axis thereof;

operably connecting a nerve monitoring system to the tool portion;

providing an electrical signal to the tip and into a patient;

rotating the tool portion relative to bone tissue of the patient;

detecting a neural element threshold of a neural element of the patient as a function of the electrical signal, wherein the detecting is performed by the nerve monitoring system; the detection based on at least one of:

monitoring a muscle reaction of the patient to the electrical signal interacting with a nerve; and

a detected increase in electrical current flowing through the tip;

stopping rotation of the tool portion upon detection of the neural element threshold to protect the neural element of the patient; wherein the stopping rotation is a result of a signal sent to the operating system in the handle portion from the nerve monitoring system.

2. The method of claim **1** wherein the operating system includes circuitry and a motor operable to rotate the tool portion about the longitudinal axis.

3. The method of claim **1** wherein the tool portion is selected from the group consisting of: a drill, a tap and a driver.

4. The method of claim **1** further comprising illuminating an area of the bone tissue via a light assembly coupled to the handle portion.

5. The method of claim **1** wherein the neural element threshold includes a proximity of the tip to the neural element.

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